DEPARTMENT OF HEALTH & HUMAN SERVICES

93683

Food and Drug Administration
466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

February 21, 2002

Warning Letter
SJN-02-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jon Borschow, President & CEO
Borschow Hospital & Medical Supplies, Inc.
GPO Box 366211
San Juan, Puerto Rico 00936-6211

Dear Mr. Borschow:

During an inspection of your firm located at 68 Calaf Street, Tres Monjitas Industrial Park, San Juan, PR, on November 1-19, 2001, our investigators determined that your firm relabels and/or distributes drug products and medical devices. Our investigators documented serious deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products as set forth in Title 21 Code of Federal Regulations (21 CFR), Parts 210 and 211. These deviations cause the drug products that you relabel, hold and distribute to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act) as follows:

1. Failure to conduct a 100 percent examination (by visual inspection) for correct labeling during or after relabeling operations in the case of hand applied cut labeling, in accordance with 21 CFR 211.122(g)(3). Such an inspection may have prevented your firm from distributing an undetermined number of bottles containing sulfur powder, which bore two labels, one identifying the product as "SULFUR SUBLIMED POWDER USP," and the other as "BICARBONATO DE SODA" (Spanish for Sodium Bicarbonate).

2. Failure to validate the computerized system used by your firm to track drug products from receipt through distribution, in accordance with 21 CFR 211.100(a). This computerized system is also used by your firm to generate the "Unique Barcode Labels" that are applied to cases containing drug products, and/or to the individual drug product containers, as part of your relabeling operation.

3. Failure to establish written procedures for the use, inspection, calibration, and/or checking of the computerized system used by your firm to track drug products from receipt through distribution, and also used in your relabeling operation, in accordance with 21 CFR 211.68(a).

4. Failure to establish and implement written procedures for the handling of all written and oral complaints regarding the drug products distributed by your firm, in accordance with 21 CFR 211.198.

Neither this letter nor the list of inspectional observations (Form FDA 483) issued to Jose L. Blanco, Vice President of Operations, at the conclusion of the inspection, is meant to be an all-inclusive list of deviations at your facility. It is your responsibility to ensure that your facility is in compliance with the provisions of the Act and all applicable regulations. Federal Agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and/or injunction.

Please notify this office, in writing, within fifteen working days (15) of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

We acknowledge receipt of a letter from Jorge R. Delgado, Quality Assurance & Process Improvement Manager, dated December 14, 2001, and addressed to Mildred Barber, Director, containing your firm's response to our FDA 483 issued on November 19, 2001. You may refer to that letter in your response to this one.

Your response should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Avenue, San Juan, PR 00901-3223, Attention: Jorge L. Gonzalez, Compliance Officer, or Carlos A. Bonnin, Compliance Officer.

Sincerely

Wayne Matthews for
Mildred R. Barber, Director
San Juan District Office